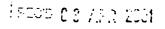
1001

PATENT COOPERATION TREATY



PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

| Applicant's or agent's file reference 92845 | FOR FURTHER ACTION | See Notification of Transmittal of International Prelimit Examination Report (Form PCT/IPEA/416). | | | |
|---|---|--|--------------------------------|--|--|
| International Application No. | International Filing Date (day/month/year) | | Priority Date (day/month/year) | | |
| PCT/AU00/01048 | 31 August 2000 | | 31 August 1999 | | |
| International Patent Classification (IPC) | or national classification | n and IPC | | | |
| Int. Cl. 7 C07K 14/22, 16/12; A61I | K 38/48, 39/095; C12 | N 15/31 | | | |
| Applicant | | DIAI DEGE : SOT | UDC ANICATION -4-1 | | |
| COMMONWEALTH SCIENT | TIFIC AND INDUST | KIAL RESEARCH C | JKUANISATIUN et al | | |
| | | | | | |
| 1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36. | | | | | |
| 2. This REPORT consists of a to | | | | | |
| been amended and are th | This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT). | | | | |
| These annexes consist of a total | These annexes consist of a total of sheet(s). | | | | |
| 3. This report contains indications relating to the following items: | | | | | |
| I X Basis of the repor | I X Basis of the report | | | | |
| II Priority | II Priority | | | | |
| III Non-establishmen | II Non-establishment of opinion with regard to novelty, inventive step and industrial applicability | | | | |
| Lack of unity of i | Lack of unity of invention | | | | |
| V X Reasoned statement citations and exp | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement | | | | |
| VI Certain documen | ts cited | | | | |
| VII Certain defects in | the international applic | cation | | | |
| VIII Certain observati | vations on the international application | | | | |
| Date of submission of the demand | | Date of completion of the | ne report | | |
| 5 March 2001 | | | • | | |
| Name and mailing address of the IPEA/AU | | Authorized Officer | | | |
| AUSTRALIAN PATENT OFFICE | 20 March 2001 ad mailing address of the IPEA/AU ALIAN PATENT OFFICE ALIAN PATENT OFFICE | | | | |
| PO BOX 200, WODEN ACT 2606, AUST E-mail address: pct@ipaustralia.gov.au | | DAVID GRIFFITHS | 3 | | |
| Facsimile No. (02) 6285 3929 | | Telephone No. (02) 623 | | | |

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/AU00/01048

| I. | | Basis of the report | |
|----|------|-------------------------------------|--|
| 1. | With | regard to the elemen | nts of the international application:* |
| | X | the international ap | plication as originally filed. |
| | | the description, | pages , as originally filed, |
| | | | pages, filed with the demand, |
| | | | pages, received on with the letter of |
| | | the claims, | pages, as originally filed, |
| | | | pages, as amended (together with any statement) under Article 19, |
| | | | pages, filed with the demand, |
| | | | pages, received on with the letter of |
| | | the drawings, | pages , as originally filed, |
| | | | pages , filed with the demand, |
| | _ | | pages, received on with the letter of |
| | | the sequence listing | part of the description: |
| | | | pages , as originally filed |
| | | | pages , filed with the demand |
| | | | pages, received on with the letter of |
| 2. | whic | n the international ap | ge, all the elements marked above were available or furnished to this Authority in the language in plication was filed, unless otherwise indicated under this item. able or furnished to this Authority in the following language which is: |
| | | the language of a tra | anslation furnished for the purposes of international search (under Rule 23.1(b)). |
| | | the language of pub | lication of the international application (under Rule 48.3(b)). |
| | | the language of the and/or 55.3). | translation furnished for the purposes of international preliminary examination (under Rules 55.2 |
| 3. | | regard to any nucleo | tide and/or amino acid sequence disclosed in the international application, was on the basis of the |
| | | contained in the inte | ernational application in written form. |
| | X | filed together with t | he international application in computer readable form. |
| (_ | | furnished subsequer | ntly to this Authority in written form. |
| | | furnished subsequer | ntly to this Authority in computer readable form. |
| | | | he subsequently furnished written sequence listing does not go beyond the disclosure in the ation as filed has been furnished. |
| | | The statement that t been furnished | he information recorded in computer readable form is identical to the written sequence listing has |
| 4. | | The amendments ha | ve resulted in the cancellation of: |
| | | the description | on, pages |
| | | the claims, | Nos. |
| | | the drawings | , sheets/fig. |
| 5. | | | established as if (some of) the amendments had not been made, since they have been considered to osure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).** |
| * | | | we been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17). |
| ** | | | ning such amendments must be referred to under item 1 and annexed to this report |
| | | | |

International application No.

PCT/AU00/01048

| ı | V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citati ns |
|---|---|
| ı | and explanations supporting such statement |
| ı | |

| and capitalitions supporting such statement | | | |
|---|-------------------------------|---------------|-----|
| 1. | Statement | | |
| | Novelty (N) | Claims 1 - 38 | YES |
| : | | Claims | NO |
| | Inventive step (IS) | Claims 1 - 38 | YES |
| | | Claims | NO |
| | Industrial applicability (IA) | Claims 1 - 38 | YES |
| | | Claims | NO |

2. Citations and explanations (Rule 70.7)

The present invention relates to antigens of *Moraxella*: peptides related to SEQ. ID. No. 1, nucleic acids encoding them, compositions containing them and antibodies raised against them.

Novelty (N) and Inventive step (IS)

WO 90/07525 discloses a cytotoxin from M. bovis that is substantially free from intact microbial cells. No sequences are given for the cytotoxin.

EP 146 523 proteases which can be used as immunoprophylactic agents for protection against *M. bovis*. No sequences are given for these proteases.

Journal of Clinical Microbiology, vol. 13, No. 2, pages 269-271, discloses hydrolytic enzymes from *Moraxella bovis*".

FEMS Microbiology Letters, Vol. 124 (1994) pages 69-73 discloses a haemolytic cell-free preparation of *Moraxella bovis* which confers protection against infectious bovine keratoconjunctivitis—no sequences are disclosed.

American Journal of Veterinary Research, Vol. 51, No. 2, pages 191 - 196 discloses leukocidic and haemolytic filtrates from *Moraxella bovis*—no sequences are disclosed.

None of the citations can be fairly said to disclose or suggest the invention defined in the present claims and so they must be acknowledges as being novel and involving an inventive step.

Industrial applicability (IA)

All claims meet the criterion of industrial applicability because they define polypeptides, nucleic acids, compositions or antibodies.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

| Applicant's or agent's file reference 92845 | FOR FURTHER ACTION | see Notification of Tra (Form PCT/ISA/220) | ansmittal of International Search Report as well as, where applicable, item 5 below | | |
|---|---|---|---|--|--|
| International application No. | International filing date | (day/month/year) | (Earliest) Priority Date (day/month year) | | |
| PCT/AU00/01048 | 31 August 2000 | | 31 August 1999 | | |
| Applicant COMMONWEALTH SCIE | NTIFIC AND INDU | STRIAL RESEAR | CH ORGANISATION et al | | |
| Article 18. A copy is being transmitted to th | e International Bureau. | l Searching Authority a | and is transmitted to the applicant according to | | |
| This international search report consists of a | | | | | |
| It is also accompanied by a | copy of each prior art doc | ument cited in this repo | ort. | | |
| 1. Basis of the report | | | | | |
| which it was filed, unless otherw | ise indicated under this it | em. | s of the international application in the language in | | |
| Authority (Rule 23.1(b)). | | | international application furnished to this | | |
| With regard to any nucleotide are carried out on the basis of the sec | nd/or amino acid sequent quence listing: | ce disclosed in the inte | rnational application, the international search was | | |
| | onal application in writter | | · | | |
| X filed together with the in | ternational application in | computer readable form | n. | | |
| furnished subsequently to this Authority in written form. | | | | | |
| 1 1 | this Authority in comput | | | | |
| application as filed has b | een furnished. | | es not go beyond the disclosure in the international | | |
| the statement that the inf furnished | ormation recorded in com | puter readable form is | identical to the written sequence listing has been | | |
| 2. Certain claims were foun | nd unsearchable (See Box | κ I). | | | |
| 3. Unity of invention is lack | | | | | |
| 4. With regard to the title, X | the text is approved as | submitted by the appli | cant. | | |
| · _ | the text has been estab | lished by this Authorit | y to read as follows: | | |
| 5. With regard to the abstract, X | the text is approved as s | ubmitted by the application | ant | | |
| | The applicant may, with submit comments to this | in one month from the Authority. | e 38.2(b), by this Authority as it appears in Box III. date of mailing of this international search report, | | |
| 6. The figure of the drawings to be pub | lished with the abstract is | Figure No. | | | |
| | as suggested by the app | | X None of the figures | | |
| | because the applicant fa | | | | |
| | because this figure bette | er characterizes the inv | ention | | |

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU00/01048 **CLASSIFICATION OF SUBJECT MATTER** Int. Cl. 7: C07K 14/22, 16/12; A61K 38/48, 39/095; C12N 15/31 According to International Patent Classification (IPC) or to both national classification and IPC FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) ANGIS: SEQ ID Nos. 1, 3, 5 ESPACE: keywords: Moraxella, antigen DOCUMENTS CONSIDERED TO BE RELEVANT Category* Citation of document, with indication, where appropriate, of the relevant passages Relevant to claim No. WO 90/07525, A1 (THE REGENTS OF THE UNIVERSITY OF CALIFORNIA (12 July 1990) Α see whole document 1-38 EP 0 146 523, A2 (NORDEN LABORATORIES) (26 June 1985) Α see whole document 1-38 Journal of Clinical Microbiology, vol. 13, No. 2, (February 1981), pages 269-271, Sandra K. Frank et al., "Hydrolytic Enzymes of Moraxella bovis". Α see whole document 1-38 Further documents are listed in the continuation of Box C X See patent family annex Special categories of cited documents: "T" later document published after the international filing date or "A" document defining the general state of the art which is priority date and not in conflict with the application but cited to not considered to be of particular relevance understand the principle or theory underlying the invention "E" earlier application or patent but published on or after "X" document of particular relevance; the claimed invention cannot the international filing date be considered novel or cannot be considered to involve an document which may throw doubts on priority claim(s) inventive step when the document is taken alone or which is cited to establish the publication date of document of particular relevance; the claimed invention cannot another citation or other special reason (as specified) be considered to involve an inventive step when the document is "O" document referring to an oral disclosure, use, combined with one or more other such documents, such exhibition or other means combination being obvious to a person skilled in the art document published prior to the international filing **"&"** document member of the same patent family date but later than the priority date claimed Date of the actual completion of the international search Date of mailing of the international search report 2 3 OCT 2000 16 October 2000 Name and mailing address of the ISA/AU Authorized officer **AUSTRALIAN PATENT OFFICE** PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au **DAVID GRIFFITHS**

Telephone No: (02) 6283 2628

Facsimile No. (02) 6285 3929

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU00/01048

| C (Continuati n). DOCUMENTS CONSIDERED TO BE RELEVANT | | | | | |
|---|---|-----------------------|--|--|--|
| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. | | | |
| | FEMS Microbiology Letters, Vol. 124 (1994) pages 69-73, F. Mark Billson et al., | | | | |
| | "A haemolytic cell-free preparation of Moraxella bovis confers protection against Infectious Bovine Keratoconjunctivitis". | | | | |
| Α | see whole document | 1-38 | | | |
| | | 1-20. | | | |
| | American Journal of Veterinary Research, Vol. 51, No. 2 February 1990' pages 191-196, Patricia S. Hoien-Dalen et al., "Comparative characterization of the leukocidic and | | | | |
| A | hemolytic activity of Moraxella bovis". | 1 | | | |
| A | see whole document | 1-38 | | | |
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INTERNATIONAL SEARCH REPORT Information on patent family members

International application No. PCT/AU00/01048

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

| Patent Do | cument Cited in Search Report | 1 | Patent Family Member | | | | |
|-----------|----------------------------------|----|----------------------|----|---------|----|------------|
| . EP | 146523 | DE | 3482442 | DK | 5950/84 | ES | 538474 |
| | | ES | 8608320 | GR | 81194 | ΙE | 57878 |
| | | JP | 60-146831 | NZ | 210490 | PT | 79640 |
| | | US | 4675176 | ZA | 8409616 | | |
| wo | 90/07525 | AU | 50886/90 | | | | |
| | | | | | | E | ND OF ANNE |